RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEITH HENRY STOCKMAN CAMPBELL
and IAN WILMUT

Appeals 2007-1617 and 2007-2989
Applications 09/225,233 and 09/658,862
Technology Center 1600

Oral Hearing Held: September 19, 2007

Before FRED E. McKELVEY, *Senior Administrative Patent Judge,* SALLY G. LANE and MARK NAGUMO, *Administrative Patent Judges.*

The above-entitled matter came on for hearing on Wednesday, September 19, 2007, commencing at 2:29 p.m., at The United States Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Christine L. Loeser, Notary Registration Number 334477, Notary Public.

A P P E A R A N C E S

ON BEHALF OF THE APPELLANT:

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PROCEEDINGS

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JUDGE NAGUMO: We will begin. We are here for appeal number 2007-1617, which is an appeal in application 09/225,233 and a related appeal in 2007-2989 regarding application 09/658,862.

Before we begin in earnest, it appears to me from the rejections and the briefing that these really are in parallel. Correct me if I'm wrong, but I don't see any really distinct argument for one application as compared to the other; is that correct?

DR. ARRIGO: I think that is correct. The arguments are the same on both sides. I anticipate arguing both of them together.

JUDGE NAGUMO: In that case, we will be treating them together and we won't have a second hearing to go over it. So why don't you begin.

DR. ARRIGO: Thank you.

The invention of the claims at issue in these appeals is a clone of a pre-existing mammal such as Dolly, the sheep. Dolly was the most extraordinary mammal of the 20th century because before Dolly, clones of living mammals were in the realm of science fiction. Not anymore.

However, according to the examiner, Dolly is the anticipator obvious over her mother. In the examiner's opinion, copies of mammals are unpatentable under sections 101, 102 and 103.

I'd like to get into the reasons why we think the examiner is wrong and before I get into these reasons, I think the first thing we should do is take a look at the claims and talk about the claims on appeal.

There are two sets of claims and within each of these sets of claims are two types of claims. The first set of claims in each case is a product by process claim, requiring a number of different process steps.

The second set of claims are pure product claims. And those claims, which I'll recite, are a liveborn clone of a pre-existing, non-embryonic or non-embryonic non-fetal donor mammal wherein the mammal is selected from a Markush group of species of mammals.

The product by process claims also contain the same type of recitation in that they are limited to a liveborn clone of a pre-existing non-embryonic or non-embryonic non-fetal donor male. So although the first set of claims might be product by process, they also contain the structural limitations to a clone.

And to look at what that claim means, we look at what is a clone. A clone is an organism descended asexually from a single ancestor. That is the textbook definition of what a clone is.

In both of the claims that we have before us today, the clone requires that the mammal descends asexually from a particular ancestor. In this particular case, it is a non-embryonic pre-existing mammal.

JUDGE NAGUMO: Well, you say descends but we are dealing -- we are thinking in classical patent terms of a product claim. Why is a clone different from an identical twin?

DR. ARRIGO: Why is a clone different from an identical twin? An identical twin is probably the closest nature makes to a clone. However --

JUDGE NAGUMO: And how is it structurally or functionally different from what's recited in the scope of these claims?

DR. ARRIGO: If I could approach the bench, and hand you a color copy of what is -- unfortunately, I can't do that electronically.

But I have color copies of what was in the brief regarding natural sexual reproduction and sematic cell cloning.

If you look at natural sexual reproduction which is what is involved in the generation of identical twins, you start with a father and a mother that have a different chromosomal make-up.

JUDGE NAGUMO: Just to make sure Judge McKelvey can be completely clued in if he wants to be, in the 1617 brief, this is at pages 7 and 8, it's the same figure, but it's in color.

Sorry. I didn't mean to throw you off.

DR. ARRIGO: Quite all right.

In the first figure, we have natural sexual reproduction shown where there's a father and a mother with a different set of chromosomes. And what happens during sexual reproduction is half of the genetic information that is going to be found in the progeny comes from the father and half comes from the mother.

Therefore, what you end up with the progeny as a mixture of the two sets of genetic information. So the progeny is not a copy of either the father or the mother.

When you have identical twins what happens is that progeny splits in half. Then you get two copies of, really of each other, not of a pre-existing mammal, but rather of -- they are copies of each other but one doesn't pre-exist the other. One is not the ancestor of the other. They are siblings.

JUDGE NAGUMO: What difference does that make in terms of the product, what they actually are? I mean, they are nuclear genetically

identical, with quotes around that, and functionally they are pretty much like any other individual.

DR. ARRIGO: In terms of a clone as compared to identical twins, if we were to have two clones here and we were to have two identical twins here, the biggest difference that you would be able to tell between them, all four of them would be different, certainly, because even identical twins are different than each other in many respects because of differences in development, differences in phenotypic changes.

For example, identical twins don't have the same iris. Identical twins don't have the same fingerprints.

JUDGE NAGUMO: But what we are trying to get at here is to understand why this product of nature theory of the examiner is necessarily so strange, given that we do have identical twins in many different species of mammals.

DR. ARRIGO: It gets down to the age difference. Identical twins are always the same age.

JUDGE NAGUMO: What difference does that make in terms of patent law?

DR. ARRIGO: I think that it makes a big difference in terms of patent law because identical twins are -- could you patent the two identical twins as separate possible patentable inventions?

I don't know how patent law really affects the patenting of identical twins. I think in this case though, in terms of something being different than nature, nature doesn't make a clone of something that pre-existed it. It simply doesn't exist in nature so you have that age difference.

JUDGE NAGUMO: I'm a little bit worried about this very, very fine distinction. Because if we take a crystal of some substance, you are not going to ever have the identical crystal.

They look quite a lot alike, but in practice, you just won't have the same crystal, at least if you get into something that is visible to the naked eye. Every crystal will be distinct from every other because they are displaced in time, if nothing else.

DR. ARRIGO: I think that's true, but how would you claim that second crystal?

JUDGE NAGUMO: Well, the same way we are claiming we have here. You would claim a process of crystallizing a certain material such that it is the same as some parent crystal.

DR. ARRIGO: Right. But I think that that would be a straight -- that would be a product by process claim.

JUDGE NAGUMO: These are product by process claims so what is it that makes them so different?

DR. ARRIGO: I would like to say that our second set of claims are pure product claims, that they are not product by process claims. Claim 163 in the 862 application and the 233 application, claim 155, don't recite any process limitations.

JUDGE NAGUMO: We have this doctrine in patent law that if the office shows that there is something that is the same or substantially the same, or appears to be the same or substantially the same, then in terms of prior art anyway, that thing is not patentable.

So it's not quite the same as the statutory double patenting -- statutory patenting issue that the examiner has made.

But it seems like a very fine distinction. Should we be making that fine a distinction? I presume you think we should. Why?

DR. ARRIGO: I think the reason you need to make that distinction is that is what the invention is all about, is what you call a fine distinction.

JUDGE MCKELVEY: Why isn't the invention a new method of making the same article?

DR. ARRIGO: It's not the same article because of the fact that it's later in time. Nature does not make copies later in time. The only time nature makes a copy is in identical twin which happens at the same time.

What is addressed by this invention which is what makes Dolly --

JUDGE MCKELVEY: So you have a process limitation in your product claim or how does this work itself out?

DR. ARRIGO: No. We do not have a process limitation in claims 155 or 163, in those two applications.

The way we work it out is, say it is a liveborn clone of a pre-existing embryonic donor mammal. So it is a --

JUDGE MCKELVEY: The product is -- isn't the product the same as the original animal?

DR. ARRIGO: No. It's actually not the same as the original animal. The differences between the product and the original animal -- the clone and the original animal are at a couple of different levels.

The first level is when you take that nucleus, and I think if you take a look at the other figure that talks about sematic cell cloning, you take that other nucleus and you put it into a foreign oocyte so there can be contributions of that oocyte to the development of that clone.

JUDGE MCKELVEY: When you say "can be," where does your claim require that that always be?

DR. ARRIGO: The fact that it is a clone.

JUDGE MCKELVEY: But I thought a clone was -- the idea of a clone was to get as close as possible to the original animal.

DR. ARRIGO: That is certainly the idea but you cannot recreate the original animal because of the fact that the environment changes that animal.

For example, with cows, when you reproduce a cow by genetic cloning, you may have one clone and its parent that look very, very different because the pigmentation patterns on their skin have not developed the same.

That's not due to the genetics. The genetics are the same, but it's due to the environmental factors having an effect on the development. So it's not the same animal.

It is a different animal. You also have an animal that will always be younger than the pre-existing animal. And I think that's really where the beauty --

JUDGE MCKELVEY: That's true if I have -- it I make benzene or just an organic compound, get my patent to it and then somebody else comes along and makes benzene. That's later in time. So does that mean that benzene is not the same as what was patented?

DR. ARRIGO: I think the difference is that we are dealing with living beings here as opposed to benzene and living beings have a certain time within which they exist, whereas benzene could potentially not have that same time frame.

JUDGE MCKELVEY: If what you say is true, then how do you distinguish over the references that show the cloned cows? What's the difference between your cow and that cow?

DR. ARRIGO: The cows in the references are clones made from embryo cloning.

What happens in embryo cloning is, if you look at natural sexual reproduction, you take that progeny embryo and you take cells from that progeny embryo or you could take that actual progeny embryo and chop it in half is a cruder way of doing the same thing and you make two progeny from that original union of sperm and oocyte. So you still have the sexual aspect of that.

You destroy the first embryo. The pre-existing donor doesn't really exist because you break it in half. There is no donor animal per se. If there could be a donor embryo, as opposed to a donor mammal, because what you could do is take cells from that progeny and put it into additional oocytes.

JUDGE NAGUMO: You seem to be distinguishing these based on the process that they are being made. I don't think we have a problem here with granting patents for different processes of doing things.

But in what way is the liveborn clone that comes from an embryonic mammal different from what you have claimed here? I mean, you have got a liveborn clone from a non-embryonic but I guess potentially fetal animal and another claim where it's neither embryonic nor fetal so it's presumably a liveborn animal.

What are the differences between these three claimed creatures, other than the way that they were made?

DR. ARRIGO: I think it has to do with the source you could call it. It's not a process limitation. It does have to do with the source and ancestor, that the ancestor of these clones is different than the ancestor of the clones made by embryo cloning.

In fact, in embryo cloning, there is no ancestor because the ancestor is destroyed in the process. You start with an embryo, destroy that embryo to make cells, to make the progeny.

JUDGE NAGUMO: Maybe it's splitting hairs but it's not necessarily the case, is it? You could take a single nucleus from an inner cell mass, in theory anyway, leaving the rest of the embryo intact, transfer that nucleus and you are off to the races.

DR. ARRIGO: There was certainly nothing in the prior art, prior to 1997 or 1996, that would indicate that that was something that was done in the prior art. Whether that could be done today I think is a different standard that shouldn't be applicable here.

JUDGE NAGUMO: So you are hanging everything on the fact that the parent in each case is somewhat different.

DR. ARRIGO: I think it also has to do with the fact that these claims require two animals. These two animals are the clone and there has to also exist or have existed a pre-existing non-embryonic donor mammal.

So there have to be two animals. And these two animals, as stated in the claims, have a certain relationship. One is the donor or ancestor of the other animal.

Now, if we compare those two animals that are required by these claims, it's a very different scenario in the prior art.

We have an animal, for example, Dolly and her mother. If we compare the embryo clones of the prior art, those would basically be a

collection of sisters or a collection of brothers. There wouldn't be an ancestor and a progeny. That's what is unique about this invention and about these claims, is that it requires these two animals.

JUDGE NAGUMO: Again, getting back to this, substantially the same theory of patent law, if we take a large field and put a bunch of animals in it and ask which of these animals are clones from any of the three processes here -- the three processes I'm thinking of specifically are the embryonic, fetal and complete individual.

How can we tell which, if any, of those clones are which clones and distinguish them from any of the other animals running around out there except by looking at who their parents happen to be? So we have to scan the entire world to see a difference, assuming that we have managed to create normal, healthy creatures.

In other words, why isn't -- is everything going back to the parenting? Are you going to put all your eggs in that basket?

DR. ARRIGO: To the parentage?

JUDGE NAGUMO: Right.

DR. ARRIGO: To compare -- certainly to compare a clone, you can't look at a clone in isolation because a clone -- clones did exist. These embryo clones did exist in the prior art. You have to have the relationship, the clone, of what.

That's what we have tried to put in the claim, clone of what.

JUDGE NAGUMO: Why then is not a new mouse patentable?

DR. ARRIGO: A new mouse.

JUDGE NAGUMO: Is it different? The mouse right over there. It's different from every other mouse that's ever been before. I mean, it's a unique individual.

DR. ARRIGO: I think it's a description issue. How do you describe that mouse? I think the only way -- I think that you could claim that mouse though, if you could deposit that mouse.

JUDGE NAGUMO: Would it be patentable subject matter?

DR. ARRIGO: I think that it would be. I don't see why not. You can certainly patent bacteria, right, if you have them in a new form. This is a new mouse that would potentially be in a new form at least in terms of its genetics.

JUDGE NAGUMO: I'll stipulate that there's nothing different about this mouse except it's different from every other mouse because it's sufficiently complex that it couldn't be the same.

DR. ARRIGO: Then I wouldn't see any problem if you could deposit that mouse and fulfill description requirements.

JUDGE MCKELVEY: Let me follow up on Judge Nagumo's comment. What would you have to prove to show infringement of your claim?

DR. ARRIGO: I think you would have to show that it fulfills all the limitations of the claim, that is it a clone --

JUDGE MCKELVEY: That's nice, but I mean, do you have to prove there was a donor and what it was and that this clone is the same as that donor?

DR. ARRIGO: It would seem to me that you would need to show that it is a clone and you would need to show what it is clone of in order to have infringement of the claim, yes.

JUDGE MCKELVEY: So if the donor is dead and gone, then what?

DR. ARRIGO: If the donor is dead and gone? Well, Dolly -- Dolly's mother was actually dead and gone when she was created. She was a six-year-old sheep who was dead and the only remnants of Dolly were plates of cells kept in the freezer. So you could look there.

JUDGE MCKELVEY: So if a smart infringer infringes your claim and gets rid of all the original cells, then how are you going to prove your case?

DR. ARRIGO: I think that's a case for the courts as opposed to a case for the PTO. It has its difficulties.

JUDGE MCKELVEY: I want to figure out whether I have got a claim that one skilled in the art can understand whether they are infringing or not.

DR. ARRIGO: I think certainly the infringer knows if they are infringing or not if they are making a clone of a pre-existing animal. They are the ones that do know the answer to that question and presumably during discovery, that could come out.

However, you are right. That's probably the only person that would know for sure what that animal is, but I don't think that's unique for this particular case.

JUDGE MCKELVEY: I'm understanding your argument, I think, here.

Now, there's also insufficient disclosure rejections here, and allegations about one way or the other that this is unpredictable and so forth and so on.

My question is, if you are successful in cloning, we'll just take Dolly, from Dolly's mother, then you could design a claim that actually identifies Dolly's mother, say, by a deposit of the cells somewhere --

DR. ARRIGO: Yes, you could potentially do that.

JUDGE MCKELVEY: -- or maintain them and then you could follow down the progeny and see if it's more or less the same as those cells and so forth.

And you would be able to say, Okay, I succeeded with that particular set of cells. What makes you so sure that the next sheep over in the next country, this will work, at least as of the filing date of this case?

DR. ARRIGO: In terms of a different sheep?

JUDGE MCKELVEY: Yes.

DR. ARRIGO: I think that the technology is very basic in terms of what's done. There's a couple of ways to do the cloning. They have to do with either using a quiescent cell in one of the cases or by using particular delayed activation in the other case to make it work.

But basically what you are doing is you are taking a nucleus and putting it into an oocyte and letting that develop into an embryo using techniques, embryonic techniques, in vitro manipulation of embryo techniques that were well known in the art at the time.

What's makes it, I think, predictable is the fact that it works with many different species under many different conditions, with one caveat and the caveat is that it is low efficiency.

JUDGE MCKELVEY: It's what?

DR. ARRIGO: It's low efficiency. You have to do this a large number of times to make it work.

JUDGE MCKELVEY: In other words, as part of the routine here, I'll have to do this a hundred times and I'll get one to function.

DR. ARRIGO: Exactly. Dolly, I believe, was 288 times to get Dolly.

What you do is you just inject a lot of oocytes. There may be financial burdens in other areas in trying to get enough oocytes to do the experiments that you need to do.

JUDGE MCKELVEY: I'm not sure that's relevant to the patentability. That may be a commercial problem.

DR. ARRIGO: Yes, exactly, and I think that that's why more species have not been cloned.

JUDGE MCKELVEY: If I'm told that I'm going to have to do this 288 times, I'm likely to get one successful, then I know going in if I'm going to use this technology, that's part of my problem.

DR. ARRIGO: Yes.

JUDGE MCKELVEY: But if I had Dolly the sheep and I had those cells, then I would look for being able to do this one out of 288, more or less. But now I go over to the next sheep. How do I know -- I mean, at what point does the 288 become a burden on the public?

I mean, if I had to do this 5,000 times, just pick a number, to get one sheep, is there a sufficient disclosure here or is the disclosure just sufficient as to Dolly?

DR. ARRIGO: No. I think the disclosure would be sufficient as to all of the species described here. In fact, it works. So far, there doesn't seem to be any species limitations with respect to the species that we have claimed. All of those species have been cloned.

JUDGE MCKELVEY: Is there testimony on this or is this your -- you are passing on what the client has told you?

DR. ARRIGO: There are papers that are of record and enablement hasn't been an issue other than the papers that are of record. There haven't been any enablement issues raised with respect to sheep, with

respect to cows, with respect to pigs or with respect to goats. The enablement issues only relate to horses, mice, rats and rabbits.

JUDGE MCKELVEY: That's because you are telling us that the prior art examiner is relying on is this embryonic thing and there's no ancestor.

Now, supposing you get past that and we are faced with the insufficient disclosure rejections on horses and the prior art is not there. Then doesn't that start to begin to apply to the animals that are mentioned in this prior art that you can assume, for purposes of discussion, we find unacceptable? The prior art is no good for the reasons you gave, say.

DR. ARRIGO: Right.

JUDGE MCKELVEY: Now what?

DR. ARRIGO: I think, again, the disclosure in the application teaches the basic methodology of nuclear transfer using somatic cells and that doesn't seem to have any species barriers.

It seems to really just be a question of there may be some different efficiencies and certainly there are techniques both in the prior art and surely into the future other techniques that will be used and can be used to improve that efficiency.

But there's certainly no evidence that shows that it doesn't work in any of those species.

JUDGE NAGUMO: I'd like to move into this mouse, rabbit, rat and horse cases because the examiner put in four papers that all postdate the filing of the application by, I think, a year and a half or two, up to about maybe six years, 2003.

They are all publications in Nature, and they are reporting an initial somatic nuclear transfer cloning success of live birth. At least, that's how I've read them. If they are not the first, please correct me.

We've got cases like Enzo v. Calgene where evidence like that has been accepted as evidence not necessarily dispositive by itself, but evidence that more than regular experimentation was necessary, the theory being that these are premier journals that refereed.

They are not necessarily completely accurate all the time but nonetheless, they wouldn't have been published there had this been a matter of routine.

And if it's not a matter of routine, that's usually an indication that undue experimentation is required.

So the examiner, I think correctly, did not accept the argument that it was their burden to show that the claimed process didn't work. Instead, the examiner came back with some evidence that perhaps indeed undue experimentation really was required for these species because the art is sufficiently uncertain.

You have to do original research, do beyond the ordinary business of just turning the crank and following the applicant's instructions. So if you could address that.

DR. ARRIGO: I'm happy to address that. I think that the reason why all of these were published very readily is that it was a new species being published and that is of public interest.

The fact that it was a different species than what had already been shown to be the first sheep that had been cloned and then cows had been cloned and there's a progression, but certainly that was of the interest to the scientific community, that another species had been cloned.

I doubt if the reviewers were aware of our patent application at the time and its disclosure that all of this could occur.

Even beyond that, if we look at the specific publications and look at what the examiner says is missing from our disclosure, either it's not missing from our disclosure or it was something that was in the prior art.

So they are combining some of the techniques that were already known in the prior art to make -- to increase efficiency.

JUDGE NAGUMO: That's hardly unusual.

DR. ARRIGO: No, it's not unusual.

JUDGE NAGUMO: Things are often available in the prior art but not necessarily at hand. That usually comes up more in the obviousness file.

But nonetheless, I think in Chesney, for example, they mention that rabbits are notoriously difficult to clone and now here they are reporting a sematic cell transfer clone.

It seems awfully easy to say, Well, we've disclosed broadly all of this stuff about how to do these clonings and not worry about all of the details of synchronizing the nucleus to the recipient cell or adjusting all the physiological factors so you can enhance your success.

If you are dealing with fairly low reproducibility events, at what point is it just a shotgun approach? We know that something can happen but we don't know how to control it enough and so we just have to do it hundreds and thousands of times.

DR. ARRIGO: I guess according to Wangs, doing things many, many times, if it's just repetitive, is not undue experimentation.

I think that that's really what we are talking about here, is just getting some additional oocytes, putting more nuclei into them, under the

conditions that are in the specifications and putting them into animals. Certainly, that's very time consuming.

JUDGE NAGUMO: How do we know that that's all that is required?

DR. ARRIGO: I think if you look at the particular publications that are cited here and you look at what did they do, compared to what's disclosed in the application, and what do they say about the increases.

I think one of the best examples is if you look at horses, that with horses, it had to do with oocyte activation and using some compounds that were known in the prior art, cycloheximide and DMAP or activation.

Both of these were very commonly used for oocyte activation in the prior art with respect to embryonic cloning so you would have known to do activation.

But if you look at that and even look at what -- the examiner says it was the combination that worked. The combination gave 93 percent activation but just with cycloheximide or just with DMAP, you got 30 percent, 31 percent and 60 percent. So again, you got a little bit better efficiency in horses with the combination.

Now, they happened to get a success with that, but wouldn't just doing it twice as many times have given it the same success if they used cycloheximide or DMAP?

JUDGE NAGUMO: That's the question. How do you know?

DR. ARRIGO: I think that everything that's in the evidence doesn't say that it won't work. Everything that is in there says that if you did it more times it should work.

In fact, there is an article cited by the examiner, West Hughsom [phonetic], which was an article in 2001 that says, At present there is no

solid evidence that suggests cloning will be limited to only a few specific animals. And, in fact, most data collected to date suggests cloning will be applicable to a variety of different animals.

The ability to reproduce any desired genotype by cloning will ultimately depend on the amount of time and resources invested in research.

Again, I think that's getting toward it's an inefficient process. You either need to invest the resources in improving your efficiency or invest the resources in the fact you are going to have to do this a large number of times.

JUDGE NAGUMO: I'd be much more willing to buy off on this argument if there were not other cases involving protein crystallization, for example, where it's -- I mean, everybody knows how to crystallize a protein but nobody is willing to go out and bet their house that they are going to have to crystallize the next protein that comes into their lab.

It's a very hit-and-miss process. You have got to do it lots and lots of times. They have robotized it so the individual strain is greatly reduced. Still it is often found that that process which I think is reasonably much simpler than cloning, creating a live birth clone anyway, is that protein crystallization process can be -- require undue experimentation.

For example, if it's a new protein, it's a protein in a different class than something that already has been crystallized that requires refinement of conditions.

DR. ARRIGO: I think that's absolutely the case.

JUDGE NAGUMO: And rarely is there anything really new that comes about doing that. They are doing the same sort of thing. They just happen to come across just the conditions that are necessary. Why isn't that the case here?

DR. ARRIGO: I think that's a very different case because, as you just said, you have to come across the conditions to use. I think in this case the conditions are in the specification, and it's simply a question of doing it many times and it will work.

If you want to tweak it and increase that efficiency, that doesn't negate the enablement of the original disclosure. Perhaps it's subject matter of an additional improvement patent on that particular tweaking that you did.

I would say that it doesn't negate the fact that the original specifications are enabling, because if you do the repetition of exactly the same experiment taught by the specifications, you will get clones. There's no evidence to say that won't work.

I think all the evidence of record says everything was successful. We increased the efficiencies by doing a few tweaks but none of that says that if you don't do this, it absolutely will not work.

JUDGE MCKELVEY: Do you have a patent to the process that appears in your claims?

DR. ARRIGO: There are a number of patents.

JUDGE MCKELVEY: No.

DR. ARRIGO: That particular --

JUDGE MCKELVEY: Does your client have a patent to that method?

DR. ARRIGO: The particular method of claims is very close to some claims that are in applications that are tied up currently. They have been allowed, that are tied up in the patent office in SAWS review.

JUDGE MCKELVEY: In Patent Office what review?

DR. ARRIGO: In sensitive application warning system review.

JUDGE MCKELVEY: Oh, okay. My thought was there, in answer to my earlier question, if you had the process claim, then you'd get the presumption the statute gives and the burden shifting, which would get back to it came from a different donor.

DR. ARRIGO: Yes. I think what the client would like to have is some composition claims simply because they are perhaps easier in terms of enforcement infringement.

JUDGE MCKELVEY: I understand that, but if part of the enforcement of the composition claims is to show the donor.

DR. ARRIGO: Yes. But it doesn't require all of the methods.

JUDGE MCKELVEY: And if you have a method claim, then you could also assert an infringement of the method claim and invoke the presumption.

DR. ARRIGO: Yes.

JUDGE MCKELVEY: Requiring the defendant to say it was a different sheep.

I'm just looking at the practical angles here of what it is we are authorizing to be allowed on whether somebody skilled in the art can figure out whether I am infringing or not.

So a lot of what I say has to do with post-issuance. But from a practical point of view, I want to know what it is I'm putting out on the public here.

DR. ARRIGO: Yes.

JUDGE MCKELVEY: So I thank you for those comments. Okay.

JUDGE NAGUMO: Any other questions from the panel?

Any final remarks?

DR. ARRIGO: I think that will do.

JUDGE NAGUMO: Thank you.

DR. ARRIGO: Thank you very much for your time.

(Whereupon, the proceedings at 3:09 p.m. were concluded.)

CERTIFICATE OF REPORTER

I, Christine L. Loeser, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

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Christine L. Loeser